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EXAMINER
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SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
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3762

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DATE MAILED: 04/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Continuation of Disposition of Claims: Claims rejected are 1-15,17-42,45-47,49,51-58,60-76,78-108,110,112-137,139-164,167-169,171,173-198,200-225,228-230,232,234-244.

Continuation of Disposition of Claims: Claims objected to are  
16,43,44,48,50,59,77,109,111,138,165,166,170,172,199,226,227,231 and233.

**DETAILED ACTION**  
***Election/Restrictions***

1. Claims 246-279 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

***Specification***

2. The disclosure is objected to because of numerous errors regarding the referencing of elements in the drawings. Furthermore, the status of the cross-referenced applications on page 1 of the specification must be updated. Correction is required. See MPEP § 608.01(b).

***Claim Objections***

3. Claims 49, 110, 171 are objected to because of the following informalities: reference to the backing layer lacks antecedent basis. The examiner will assume dependency on claims 48, 109 and 170 respectively. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 49, 110, 171 and 232 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.  
Reference to the backing layer lacks antecedent basis.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:  
A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 4, 5, 8, 9, 11, 12, 14, 21, 22, 40-42, 45-47, 56, 57, 62, 65, 66, 69, 70, 72, 73, 75, 82, 83, 95, 101-103, 106-108, 117, 118, 123, 126, 127, 130, 131, 133, 134, 136, 143, 144, 156-158, 162-164, 167-169, 178 and 179 are rejected under 35 U.S.C. 102(b) as being anticipated by Moe, Jr. (Pat. No. 3,566,860).

Regarding claim 1, Moe, Jr. shows an electrode 12 coupled to a riser 14 with a head 16 coupled to the riser. While the preamble was considered, the reference to subcutaneous implantation was considered to be merely a statement of intended use absent any structure in the body of the claim that would limit the lead electrode to this locale.

Regarding claim 41 and claims with similar limitations, where one measures length by no means limits the apparatus in any way structurally.

Regarding claim 42 and claims with similar limitations, the examiner will consider in this instance the proximal end of the electrode to be the topside of the electrode 12, and the distal end to be the bottom-side of electrode 12.

Regarding claim 45 and claims with similar limitations, the examiner considers element 18 to comprise a foundation. One could also consider elements 26 and 28 to comprise a foundation.

Regarding claim 46 and claims with similar limitations, since one may arbitrarily define what is a top surface of the foundation and what is a bottom surface of the riser, the recited relationship can always be met.

Regarding claims 62 and 123, note the comments made in the rejection of claim 1 concerning preamble interpretation.

6. Claims 1-3, 6, 7, 11, 12, 14, 19-22, 40-42, 45, 46, 63, 64, 67, 68, 72, 73, 75, 80-83, 106, 123-125, 128 and 129 are rejected under 35 U.S.C. 102(b) as being anticipated by Corasanti (Pat. No. 3,841,312).

The rejection of claims under Corasanti substantially parallel the rejection of claims under Moe, Jr. with the exception that the lead electrode assembly of Corasanti is made out of metal (particularly a nickel alloy).

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4. Claims 1, 2, 6, 10-14, 19, 21, 22, 24-28, 34, 40-42, 45-47, 56-58, 62, 63, 67, 71-75, 80, 82, 83, 85-89, 95, 101-103, 106-108, 117-119, 123, 124, 128, 132-136, 139, 141, 143, 144, 146-150, 156, 162-164, 167-169, 178-180 and are rejected under 35 U.S.C. 102(b) as being anticipated by Lemole (Pat. No. 4,553,554).

See Fig. 4, element 20.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 15, 17, 18, 23-39, 51-55, 60, 61, 76, 78, 79, 84-94, 96-100, 104, 105, 112-116, 121, 122, 137, 139-142, 145-155, 159-161, 173-177, 182-184, 187, 188, 191, 192, 198, 200, 201-225, 228-230, 234-244, are rejected under 35 U.S.C. 103(a) as being unpatentable over Moe, Jr. (Pat. No. 3,566,860).

With reference to claim 15 and claims with similar limitations, although Moe, Jr. does not concern himself with the length of the riser, the examiner considers the riser of Moe, Jr. to necessarily fall within the recited range based on obvious design constraints. Clearly one would not manufacture a riser for use in the system of Moe, Jr. that is so long that it sacrifices the stability of the electrode on the body (i.e., acting like a cantilever beam with the force of the lead pulling the electrode off the body due to the higher torque associated with the increased length). Nor would one manufacture a riser that is so short as to make it difficult to attach a lead to the head.

Concerning claims 17 and 18 as well as claims with similar limitations, the examiner did not require restriction between embodiments wherein the electrode was a mesh or a flat sheet or a polymer or a metal because such variations were not considered to be patentably distinct. Since the examiner has found the embodiment comprising a flat sheet, the use of a metal mesh is also considered to be an obvious variant.

Concerning claim 23, although Moe, Jr. does not elaborate on the exact dimensioning of the electrode area, the examiner takes Official Notice that electrodes of the type disclosed by Moe, Jr. typically would have a surface area falling within the recited range.

Regarding claims 24-28 and claims with similar limitations, although Moe, Jr. does not show the use of a lead coupled to the electrode, the use of such a lead is an absolute necessity if the device is to function. The examiner takes Official Notice that leads of this nature comprise one or more electrical conductors surrounded by insulation.

Concerning claim 29, the examiner considers a typical lead for use in the Moe, Jr. system to fall in the range recited and takes Official Notice to this effect. Likewise concerning claims 30 and 31, no criticality has been recited by the applicant for the particular length of lead used. The examiner considers it a matter of obvious design as to what the final lead length should be, dependent upon the situation at hand (e.g., an electrode vest with integrated leads would not require a lengthy cable to connect each electrode to the monitor).

Concerning claims 32 and 33, the applicant appears to be defining the invention in terms of non-elements of the invention. The applicant is not claiming a set of leads with a plurality of preset lengths varying by approximately 10 cm –simply that the lead used is one of a plurality of preset lengths. Whether a lead falls into this category is simply a matter of how many different leads a manufacturer may produce.

Regarding claims 34 and 35, the examiner considers it axiomatic that any lead used in the device of Moe, Jr. would have a proximal end and a distal end, with at least one end coupled to the electrode via a lead fastener.

Regarding claims 36-38, since one can arbitrarily define a line in any direction, there are an infinite number of lines along which the riser is connected to the electrode. One for example can define a line through the axis of the riser and consider such a line to encompass a point at which the riser is attached to the electrode and also intersects the lead fastener.

Regarding claim 39, considering the relatively large range recited and typical neck or riser lengths associated with electrodes of the type disclosed by Moe, Jr., those of ordinary skill in the art would have found it axiomatic that the riser of Moe, Jr. be within this recited range for practicality purposes.

Concerning claims 51 and 52, although Moe, Jr. shows a cover (element 18), it is not clear that it is molded. The examiner takes Official Notice that it is old and well-known in the prior art of record to produce an element such as shown by reference numeral 18 by molding processes. In this instance, the examiner considers elements 26 and 28 to represent a foundation.

Regarding claim 53, since one can arbitrarily define what is to be the top and the bottom of the electrode, the examiner considers the cover 18 to be a skirt that partially covers a bottom surface of the electrode (it should be noted that the skirt shown in Fig. 4 does not completely overlie the electrode about the riser/neck 14).

Regarding claim 184, while Moe, Jr. does not explicitly discuss the use of a housing, clearly since the electrode of the device is intended to be connected to monitoring equipment (see col. 1, lines 63-75), and since such equipment demands a housing to protect the circuitry within, those of ordinary skill in the art would have seen the provision of such a necessary housing as blatantly obvious. Although the preamble's reference to a defibrillator was considered, the body of the claim contains no structural recitation limiting the device to such an application. The preamble therefore fails to give "life and meaning" to the claim as a whole.

Regarding claim 218, the examiner considers the requisite snap fastener to connect the lead to the electrode to constitute a lead fastener.

5. Claims 59, 81, 120, 181, 184-186, 189, 190, 193-197, 202-205, 207-211, 217, 223-225, 228-230, 239-242 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemole (Pat. No. 4,553,554).

Regarding claims 59, 81, 120 and 181, while Lemole teaches to employ stainless steel (see col. 3, lines 15 and 16), there is no discussion of stainless steel alloys, platinum, titanium, etc.. Clearly the particular choice of metal used in the construction of the Lemole electrode would have been considered a matter of obvious design, with any

known biocompatible, non-reactive, conductive material being suitable to the invention (again see col. 3). Since all the materials listed in the claims of interest are old and well-known to those of ordinary skill in the medical electrode arts, their incorporation into the device of Lemole would have been considered blatantly obvious by the ordinarily skilled artisan.

Regarding claim 184, Lemole discloses a lead electrode assembly comprising an electrode 20 with a riser coupled to the electrode and a head coupled to the riser (see Fig. 4). Although Lemole does not explicitly refer to the use of a housing (instead simply stating that the lead electrode assembly is connected to a pacemaker device), the use of a housing to encapsulate and protect sensitive pacer circuitry would have been considered blatantly obvious by those of ordinary skill in the cardiac stimulation arts. Such means are ubiquitous in the art.

Although the preamble's reference to a defibrillator was considered, the body of the claim contains no structural recitation limiting the device to such an application. The preamble therefore fails to give "life and meaning" to the claim as a whole.

#### ***Allowable Subject Matter***

10. Claims 16, 43, 44, 48, 50, 59, 77, 109, 111, 138, 165, 166, 170, 172, 199, 226, 231, 233 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Claims 49, 110, 171 and 232 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

12. The lengthy IDS submitted on November 14, 2003 was not accompanied by any of the listed references and therefore does not meet the requirements of §1.98.




12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaezle whose telephone number is 703 308-2211. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0858.

KJS  
April 26, 2004



KENNEDY SCHAEZLE  
PRIMARY EXAMINER